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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,018	06/27/2001	Alessandro Sette	2060.0320003	7107

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EXAMINER

MARSCHER, ARDIN H

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

**Application No.**

09/894,018

**Applicant(s)**

SETTE ET AL.

**Examiner**

Ardin Marschel

**Art Unit**

1631

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 and 38-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's election with traverse of Group II (claims 27-37) in the Paper, filed 12/9/03, is acknowledged. The traversal is on the ground(s) that searching the inventions of Group I and II together would not be a serious burden. In response firstly applicants seem to be characterizing Group II as a method of using a computer system. Confusingly, there is not a single computer system limitation anywhere in the claims of Group II. Thus, it is non-persuasive that Group II requires the computer system of Group I as no such requirement is present in the Group II claims. Therefore, a search for the subject matter of Group II does not necessarily disclose the computer system of Group I. Applicants then argue that the insertion of amino acids to minimize junctional epitopes is a concept common to both Groups. In response, this insertion practice is not seen in claim 1 of Group I, nor in any other claims of Group I. Rather the invention of Group I cites the insertion of amino acids to generically optimize the construct. Thus, the invention is Group I is directed to optimization of amino acid insertions whereas distinctly, and of distinct subject matter, Group II includes the minimization of such insertions regarding junctional epitopes. Thus, this argument is contrary to the factual subject matter between Groups I and II and therefore is non-persuasive.

The requirement is still deemed proper and is therefore made FINAL.

### **SEQUENCE RULE NON-COMPLIANCE**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§1.821(a)(1) and (a)(2). See, for example, sequences on pages 34 and 79 of the

specification with 6 amino acids but without SEQ ID NOs. However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 because it lacks SEQ ID Nos with the above noted sequences. If necessary, applicants must submit a new computer readable form sequence listing, a paper copy for the specification, a statements under 37 CFR §§ 1.821(f) and (g), and SEQ ID Nos cited along with each sequence in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

#### **VAGUENESS AND INDEFINITENESS**

Claims 27-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The presence of abbreviations in claims without the generic name therewith causes claims to be vague and indefinite as to what is meant. Claim 27 cites the abbreviations CTL, HLA, K, R, N, etc. These abbreviations and others are present in most of claims 27-37 and are equally vague and indefinite. Claims which depend from claim 27 directly or indirectly which thus also contain the above unclarities are also rejected hereinunder due to their dependence. Clarification via clearer claim wording is requested.

The preamble of claims 27 and 28 state that the designed construct “is” presented to an HLA Class I processing pathway”. Confusingly, none of the actual claim steps are directed to such presenting practice. Thus, it is confusing as to whether the preamble method which includes such presenting or the claim steps (i) – (iv) (claim 27) or steps (i) – (iii) (claim 28) control the metes and bounds of the claim practice. Claims which depend from claim 27 directly or indirectly which thus also contain the above unclarities are also rejected hereinunder due to their dependence. Clarification via clearer claim wording is requested.

Similarly, claim 37 contains the optional limitation “when introduced into a cell” which is unclear as to whether the required claim steps require such introducing or not. Clarification via clearer claim wording is requested.

Claim 27, step (i), cites the sorting of epitope nucleic acid to minimize the number of junctional epitopes. This causes the claim to be vague and indefinite as to the conflict between sorting and minimizing. A sorting step is reasonably a step wherein items in a list such as epitope nucleic acids are arranged in an order such as by the number of junctional epitopes. Such sorting does not minimize the content of any item on the list. It is acknowledged that the list may be sorted so that a subset, possibly an epitope at the top or bottom of the list has the fewest number, or a minimum of junctional epitopes, but that this does not change the number of epitopes either for such an item or for the list which is what is indicated by minimizing a number. Minimizing a number, such as junctional epitopes, is reasonably interpreted as a reduction of such epitopes to a minimum number. Sorting conflicts with such a reduction and thus makes

the claim vague and indefinite. Claim 28 also contains this unclarity. Claims which depend from claim 27 directly or indirectly which thus also contain the above unclarity are also rejected hereinunder due to their dependence. Clarification via clearer claim wording is requested.

In claim 27, step (ii), the phrase "a CTL epitope nucleic acids" is internally conflicting in that "a CTL epitope" is singular vs. "acids" which is plural. The conflict in wording causes the interpretation thereof to be vague and indefinite. Claims which depend from claim 27 directly or indirectly which thus also contain the above unclarity are also rejected hereinunder due to their dependence. Clarification via clearer claim wording is requested.

In claim 27, steps (ii) and (iii) the introduction of amino acids is cited but is unclear what flanking vs. spacer amino acids are meant when the introduction apparently is meant to minimize junctional epitopes. It is noted that a junctional epitope is defined in the specification as an epitope wherein two other epitopes are juxtaposed. Is the flanking amino acids for each such juxtaposed epitopes also a spacer amino acid if it flanks one epitope but is also between the two juxtaposed epitopes. This unclarity is also present in claim 28. Claims which depend from claim 27 directly or indirectly which thus also contain the above unclarity are also rejected hereinunder due to their dependence. Clarification via clearer claim wording is requested.

In claim 27, step (iv), there are three criteria, two minima, and one maximum. The minima appear to conflict in that minimizing junctional epitopes apparently is performed via amino acid spacer insertions where as minimizing amino acid spacer

residues would maximize junctional epitopes. Clarification of this internal conflict is requested via clearer claim wording. Claims which depend from claim 27 directly or indirectly which thus also contain the above unclarities are also rejected hereinunder due to their dependence.

### INFORMATION DISCLOSURE STATEMENT

The information disclosure statement, filed 3/12/02, listed a lengthy series of U.S. Patent Applications, which are hereby acknowledged as having been considered.

No claim is allowed.

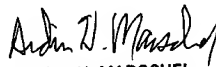
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571)272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571)272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 20, 2004

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER